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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/534,789	10/11/2005	Henri Tiedge	1181-13 PCT US	2634

28249 7590 03/14/2008

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EXAMINER	
WOLLENBERGER, LOUIS V	

ART UNIT	PAPER NUMBER
1635	

MAIL DATE	DELIVERY MODE
03/14/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/534,789	TIEDGE, HENRI	
	Examiner	Art Unit	
	Louis Wollenberger	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 December 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) *5,6 and 8-16* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4, 7, and 17-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *13 May 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/24/06; 11/30/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election of Group I in the reply filed on 12/20/2007 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Upon further consideration, the Restriction between Groups I and II and between III and IV is withdrawn. Group II is rejoined with Group I for prosecution on the merits. Group III is rejoined with Group IV. As to all other Groups, the Restriction is still deemed proper and is made final.

Applicant's representative, Ann Pokalsky, was contacted by phone on 2/27/08, to invite election of either SEQ ID NO:3 (Group III), which embraces SEQ ID NO:4 (Group IV), or SEQ ID NO: 5 (Group V) for prosecution on the merits with rejoined Groups I and II.

On 2/28/08, Ms. Pokalsky elected by phone, on applicant's behalf, SEQ ID NO:3 and 4, recited in claims 3 and 4.

Claims 1-19 are pending.

Claims 5, 6, and 8-16 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Claims 1-4, 7, and 17-19 are examined herein.

Claim Objections

Claims 6 and 17-18 are objected to for being drawn to non-elected subject matter.

Specifically, the claims expressly include the embodiment of Group VI, claim 6.

Statutory Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 3 and 4 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 2 and 3 of prior U.S. Patent No. 5,670,318. This is a double patenting rejection.

Non-Statutory Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 2, 7, and 17-19 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7 of U.S. Patent No. 5,670,318 in view of Ely et al. (1995) "Preparation of Nonradioactive DNA probes" in *Methods in Molecular Biology* Vol. 46, pp. 201-211, Humana Press, ISSN 1064-3745.

U.S. Patent 5,670,318 claims oligonucleotide probes that specifically hybridize to residues 156-185 of a human BC200 RNA identical to instant SEQ ID NO:1 and 2. US Patent 5,670,318 further claims oligonucleotide probes identical to instantly claimed SEQ ID NO:3 and 4. The '318 therefore anticipates the genus of antisense oligonucleotides claimed in instant claims 1 and 2, as the '318 patent specifically claims one or more species thereof. A generic claim cannot be allowed to an applicant if the prior art discloses a species falling within the claimed genus." The species in that case will anticipate the genus. *In re Slayter*, 276 F.2d 408, 411, 125 USPQ 345, 347 (CCPA 1960).

With regard to instant claims 17-19, drawn to isolated antisense oligonucleotides in pharmaceutically acceptable carriers and to kits thereof, it was well known in the prior art to package probes and other diagnostic reagents, routinely used in the laboratory, in the form of kits to save time and expense. Further, the term "Kit" is not limited by either the claims or the specification to commercially purchased materials but is broadly interpreted to include any compartmentalized arrangement of the probes in enclosed vessels and/or carriers prepared by the artisan according to routine practice.

With regard to claims 7 and 17-19, the '318 Patent does not specifically claim admixtures of the probes in pharmaceutically acceptable carriers. However, the instant application defines "pharmaceutically acceptable carriers" at page 35 as "any and all solvents, buffers, dispersion media, coatings, antibacterial and antifungal agents, isotonic and absorption delaying agents, and the like that are non-toxic to a subject." Additionally, it was well known in the prior art to conclude the purification of DNA probes by resuspending the DNA probes in water or Tris-EDTA prior to use in blotting and hybridization-based detection assays. See, for example, Ely et al. (page 205). Absent evidence to the contrary, these solvents, among the many known in the art, are considered to be "pharmaceutically acceptable" carriers or diluents. Thus, this limitation fails to distinguish the claimed invention over that claimed in US Patent 5,670,318.

Therefore, one of ordinary skill in the art would conclude that the invention defined in the claims at issue is anticipated by, or would have been an obvious variation of, the invention defined in a claim in the conflicting patent.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Tiedge et al. (US Patent 5,670,318).

Tiedge et al. disclosed a BC200 RNA target sequence identical to instant SEQ ID NO:1 and DNA probes complementary to said sequence. More specifically, Tiedge et al. disclosed oligodeoxynucleotide probes identical to instantly claimed antisense sequences SEQ ID NO:3

and 4 (see the sequences set forth at the top of column 3). Additionally, Tiedge et al. specifically taught probes complementary to instant SEQ ID NO:2 (see column 2, bottom).

While Tiedge et al. do not specifically teach using these probes for inhibition of BC200 RNA expression, the structures, i.e., the exact sequences, were, nevertheless, disclosed. Therefore, all properties inherent to these sequences, whether recognized or not, were disclosed and in the public domain more than one year before the filing date of the instant application. Because the disclosed sequences are identical to those now claimed in claims 3 and 4, the disclosed sequences necessarily possess antisense properties and *de facto* are antisense to the target recited in instant claims 1 and 2. For example, instant SEQ ID NO:4 is identical to SEQ ID NO:7 in Tiedge et al., which specifically hybridizes with instant SEQ ID NO:1 and 2, also identical to SEQ ID NOs. 1 and 2, respectively in Tiedge et al.

[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977).

There is no requirement that a person of ordinary skill in the art would have recognized the inherent disclosure *at the time of invention*, but only that the subject matter is in fact inherent in the prior art reference. *Schering Corp. v. Geneva Pharm. Inc.*, 339 F.3d 1373, 1377, 67 USPQ2d 1664, 1668 (Fed. Cir. 2003).

Applicant is not claiming a method of use, but the product itself. The term "antisense", used in the instant claims, is merely an intended use that does not clearly impose any structural limitations distinguishable from those sequences set forth by Tiedge et al. Clearly, the claimed antisense molecules include those disclosed by Tiedge et al. as evidenced by a comparison of the sequences claimed in instant claims 3 and 4 with those disclosed by Tiedge et al. for use as diagnostic probes.

With regard to the genus claimed in claims 1 and 2, A generic claim cannot be allowed to an applicant if the prior art discloses a species falling within the claimed genus." The species in that case will anticipate the genus. *In re Slayter*, 276 F.2d 408, 411, 125 USPQ 345, 347 (CCPA 1960).

Accordingly, Tiedge et al. disclosed each and every aspect of the instantly claimed products.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 7 and 17-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tiedge et al. (US Patent 5,670,318) as applied to claims 1-4 above, and further in view of Ely et al. (1995) "Preparation of Nonradioactive DNA probes" in *Methods in Molecular Biology* Vol. 46, pp. 201-211, Humana Press, ISSN 1064-3745.

Tiedge et al. is relied on for the reasons given above in the rejection of claims 1-4 under 35 USC 102.

Tiedge et al. further taught formulating/packaging said antisense probes in kits (see col. 1, bottom, and col. 5, lines 38-65).

Tiedge et al. do not expressly teach diluting or solvating the disclosed probes in "pharmaceutically acceptable" carriers. However, in view of the definition given at page 35 of the instant specification, embracing any non-toxic buffer or solvent, and in view of the protocols disclosed in the prior art establishing that it was routine and customary for practitioners to prepare DNA probes in non-toxic buffers such as water and Tris-EDTA, for example (see Ely et al.), it would have been obvious to one of skill in the art at the time that the types of buffers and solvents implicitly and inherently disclosed and suggested by Tiedge et al. for making and storing the anti-BC200 DNA probes would necessarily be pharmaceutically acceptable inasmuch as they would be compatible with at least one use in vivo.

Accordingly, the mere formulation of the claimed antisense oligonucleotides in a pharmaceutically acceptable carrier *per se* does not patentably distinguish the claimed products over those disclosed by Tiedge et al. Moreover, specific motivation to formulate in a pharmaceutically acceptable carrier is not particularly relevant since it would have been clear to

the ordinary practitioner the probes disclosed by Tiedge et al. must be dissolved in some buffer or solvent and that many buffers and solvents, and since there is evidence to suggest (Ely et al.) that at least one acceptable buffer known in the prior art for use with probes included a solvent likely to be pharmaceutically acceptable.

Thus, in the absent of convincing evidence to the contrary, the instantly claimed invention would have been *prima facie* obvious to one of skill in the art at the time the invention was made.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Louis Wollenberger whose telephone number is (571)272-8144. The examiner can normally be reached on M-F, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Schultz can be reached on (571)272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Louis Wollenberger/
Examiner, AU1635
February 27, 2008